K011557

JUL 1 2 2001

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

June 11, 2001

*Submitted By:* NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491
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*Contact Person:* Nichelle LaFlesh

*Device Name:* All NuMED Catheters

*Predicate Devices:* All NuMED Catheters

*Biocompatibility Testing:* The only material that has changed is the new bifurcate cover. This cover is made of PVC material. The testing that was done on this new material in enclosed in the biocompatibility section of this submission. All other materials have not changed from the original submissions and testing is on file at NuMED, Inc..

*Laboratory (Bench) Testing:* All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

| Bench Testing Performed | Acceptance Criteria |
|---|---|
| 1. Balloon Deflatability | Deflation achieved in less than 20 seconds. |
| 2. Inflation/ Deflation Times Test | Inflation and deflation achieved in less than 10 seconds. |
| 3. Repeated Balloon Inflation (Balloon Fatigue) Test | Each diameter taken up to rated burst forty times without breaking. |
| 4. Bond Integrity | Minimum of 3 lbs. at all test points. |

*Comparison Information:*

**Current Design**

The current design of the NuMED Y connector involves the use of several molded parts that are purchased from Dr. Osypka GMBH in Germany. NuMED catheters are basically coaxial in construction. This construction consists of an outer tubing that has a distally mounted balloon on the end. An inner tubing runs the entire length of the catheter and allows access throughout the catheter for a guidewire to be passed. The area between the inner and outer tubing is utilized for the inflation of the balloon. During the catheter construction, a molded Silicone part called a strain relief and a molded part called the M4 nut are threaded onto the proximal end of the outer shaft. This outer shaft is then fitted with a flared tubing section (trumpet) on the proximal end. This trumpet is heat bonded

to the tubing. The M4 nut (which has an internal thread is then pulled to the end of the tubing and in turn the trumpet is positioned in the M4 nut. This assembly is the outer tubing assembly.
In a similar manner, the inner tubing is fitted with a trumpet on the proximal end. This inner tubing with trumpet is threaded through a molded Y connector that consists of a distal extension section with an internal thread and a proximal section with an external thread. The Y connector also has a balloon inflation extension that empties into the Y cavity and out the distal end of the Y. The inner tubing is threaded through the distal extension until the trumpet is seated at the bottom of the distal extension. This trumpet seats just below the internal thread. At this point, an externally threaded screw cap is screwed into the distal extension. When the threads are tightened to a set torque the bottom of the screw cap is pressed tightly against the trumpet. This forms an air and liquid tight seal into the inner tubing through the luer lock screw cap. The inner tubing passes through the Y connector and isolates the interior of the inner lumen from the entire system.
This inner assembly (with Y connector) is then threaded into the outer assembly. The external threads on the Y connector are then screwed into the internal threads on the M4 nut. This will give an airtight seal from the balloon inflation extension, through the Y connector and into the outer tubing ending in the balloon. At this time the strain relief is fitted to the distal end of the M4 nut. All threaded parts are then sealed with adhesive. The distal tip of the balloon is then sealed and two distinct passages are formed. One passage from the end of the balloon extension, through the Y connector cavity, through the outer tubing and into the balloon. The other passage starts at the distal luer lock screw cap, through the inner tubing and out the tip of the catheter.

**New Design**

With the new construction of the catheters, most of the above mentioned parts are eliminated. The catheters are still coaxially constructed in the same manner as above except at the initial point, the inner and outer tubings and balloons are attached together with the balloon and tip bonded together. The balloon extension and guidewire extensions are manufactured before the actual Y is made. The Y is constructed by threading a Y cover sleeve on to the outer body along with a section of silicone molding tubing. An internal wire (TFE Coated) is inserted through each extension and these wires are inserted into the inner lumen and the area between the lumens, respectively. The extensions are then butted up against the catheter assembly. This junction is covered with the silicone molding sleeve. Heat is applied (usually approx. 600°F) to the silicone allowing the tubings to soften and flow together as molded by the silicone tubing. The internal passages are kept open by the internal mandrils. This junction is then cooled and the silicone mold is cut off. The Y cover sleeve is then pulled into position to cover the junction. This cover sleeve has an elongated portion that extends distally. This portion will provide strain relief for the junction as well as a cover for the Y connector.

Important Considerations

- The catheter distal section that enters the body has not changed in any manner. Any blood contact part will be exactly the same as the previous design.

- The new Y connector design is used currently in several other applications including the PTS and Septostomy catheter.
- This manner of attaching proximal extensions has been being used in catheter manufacturing for more than 10 years. Most Y's were covered with heat shrink but we are covering ours with a molded PVC sleeve.
- The new Y connectors will be less prone to leakage and will be as stronger as the tubing that they are manufactured from due to the increase in wall thickness.
- The new Y connector method will eliminate the use of adhesive on any parts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Nichelle R. LaFlesh
Regulatory Affairs Manager
NuMed, Inc.
P.O. Box 129
Nicholville, NY 12965

Re: K011557
PTA, PTV, Atrioseptostomy, Angiographic, Sizing Catheters
Regulation Number:
Regulatory Class: II
Product Code: 74 DXF, 74 DQO and 74 LIT
Dated: June 11, 2001
Received: June 12, 2001

Dear Ms. LaFlesh:

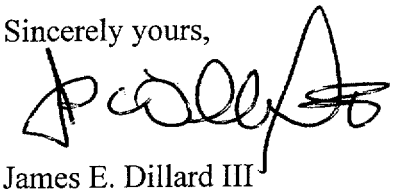
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications For Use

## 510(k) Number (if known): K011557

Device Names: Multi-Track Angiographic Catheter, Ghost II PTA Catheter, Z-MED Catheter, Tyshak Mini Pediatric PTV Catheter, Tyshak Catheter, Tyshak II Catheter, Z-MED II Catheter, Z-5 Atrioseptostomy, High Pressure PTA Catheter

Indications For Use: **Multi-Track Angiographic Catheter** - Recommended for use in catheterization for angiography of cardiovascular vessels and/or chambers. It can be used for injection of contrast medium and pressure measurement in any chamber or vessel.

**Ghost II PTA** - This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

**Z-MED Catheter** - This catheter is recommnded for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not requrie surgical intervention. And;

This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

**Tyshak Mini Pediatric PTV Catheter** - This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications.

- A patient with isolated pulmonary stenosis.
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

**Tyshak Catheter** - This catheter is recommnded for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not requrie surgical intervention. And;

This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

**Tyshak II Catheter** - This catheter is recommnded for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not requrie surgical intervention. And;

This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

**Z-MED II Catheter** - This catheter is recommnded for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not requrie surgical intervention. And;

This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

**High Pressure PTA (Marauder)** - This catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, and renal arteries. **These catheters are not designed to be used in the coronary arteries.**

**Z-5 Atrioseptostomy** - Used for the palliation of several congenital heart defects: transposition of the great arteries, total anomalous pulmonary venous drainage without pulmonary obstruction, tricuspid atresia, mitral stenosis, mitral atresia, and pulmonary atresia with intact ventricular septum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K01557

(Optional Format 1-2-96)